

Criminal No. 1:21-cr-10256-IT

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Defendants Kingsley R. Chin, Aditya Humad, and SpineFrontier, Inc. respectfully submit this memorandum in support of their motion to dismiss Count One of the Indictment, which charges them with a conspiracy to violate the Anti-Kickback Statute (“AKS”), and Counts Two through Seven, which charge them with substantive violations of the AKS. In the event the Court does not find it appropriate to dismiss on the papers, the defendants respectfully request an evidentiary hearing concerning the government’s awareness of exculpatory information when it presented contrary information to the Grand Jury, along with an *in camera* inspection of Grand Jury transcripts that the government has withheld, including the legal instructions the government provided to the Grand Jury.

Preliminary Statement

The Indictment presents cumulative prejudice from improper Grand Jury processes and a failure to comply with *Brady* obligations that the Court has ordered. While prosecutors have reasonable discretion before a Grand Jury and no general duty to present exculpatory evidence, their discretion is not without limitation. Three fundamental Grand Jury rules of constitutional magnitude are implicated here: (1) prosecutors cannot present materially false information to mislead a Grand Jury; (2) prosecutors cannot deceive a Grand Jury through summaries based on unreliable hearsay; and, (3) prosecutors cannot “seriously misstate” applicable law in a manner that casts “grave doubt” on whether the decision to indict was free from the improper influence of their having done so. Cumulative violations of these rules tainted the Indictment. The applicable test on this motion is not whether the Indictment adequately alleges the elements of charged offenses, but whether there is a “substantial likelihood” that misleading legal or factual information influenced the Grand Jury’s decision to indict. These problems are compounded by the government’s failure to comply with two Orders requiring them to satisfy their *Brady* obligations.

The Indictment essentially breaks the AKS charges into two components: (1) whether

SpineFrontier implemented the use of an affiliate, Impartial Medical Experts, LLC (“IME”), to evade reporting requirements under the Physician Payments Sunshine Act, and (2) whether failures of physicians to perform contractual obligations establish willful AKS violations by each of the defendants. The Indictment accuses Chin, Humad, and SpineFrontier of using IME in part to evade Sunshine Act reporting obligations and thus to conceal the true nature of the relationship between SpineFrontier and surgeons that it paid as consultants. The government intervened in a related (now-resolved) civil action on behalf of the United States Department of Health and Human Services (“HHS”) (through its Centers for Medicare and Medicaid Services (“CMS”)), similarly alleging that SpineFrontier used IME to evade reporting requirements under the Sunshine Act. In that civil action, the government identified CMS as the primary victim. CMS’s role in federal healthcare programs is also alleged extensively in the Indictment.

The government has relied on a theory that SpineFrontier used IME to evade reporting requirements, in order to portray failures by physicians to provide adequate consulting as willful criminal conduct rather than mere breaches of contract. Under well-established legal principles, mere failures to perform a contract do not give rise to inferences of criminal culpability.¹ To cast doctors’ failures to perform as alleged crimes by the defendants, the government advanced a false theory that SpineFrontier used IME to evade reporting obligations, and relied on inaccurate presentations to the Grand Jury to do so. As described in more detail below, contrary to the allegations in the Indictment, it is indisputable that SpineFrontier in fact made proper disclosures *in its own name*. Consistent with the Sunshine Act, SpineFrontier made 733 such public

¹ “[T]he fact of COSVI’s failure to write the letter,” as required by a settlement agreement, “does not support the conclusion that COSVI was acting in bad faith.” *F.A.C., Inc. v. Cooperativa De Seguros De Vida De Puerto Rico*, 563 F.3d 1, 7 (1st Cir. 2009); *Seward v. Hammond*, 8 F.R.D. 457, 459 (D. Mass. 1948) (“[A] failure to perform the terms of a contract, without more, does not constitute fraud within the meaning of the Securities Exchange Act.”).

disclosures since 2016 (the first year for which there is information available through a CMS public portal). SpineFrontier made more than 1,000 such disclosures since 2013, but those before 2016 are not currently available on the public portal. Importantly, the government has not challenged, in the Indictment or otherwise, the legality of SpineFrontier's consulting contracts with surgeons at issue. Rather, the government alleges that the consulting surgeons failed to perform their obligations under the contracts and instead received payments in exchange for insufficient value.

It is axiomatic that a mere failure by physicians to perform under consulting agreements cannot equate to willful violation of the AKS by the defendants. To close the gap, and to obtain the Indictment, the government made a misleading presentation to the Grand Jury about the use of IME to evade Sunshine Act reporting requirements. Under the circumstances, there is a substantial likelihood that misleading information influenced the Grand Jury's decision to indict. This case is thus the rare prosecution in which an Indictment must be dismissed because of prosecutorial misconduct before the Grand Jury. If a more complete record is needed, this Court should hold an evidentiary hearing regarding the government's awareness of SpineFrontier's disclosures and threats to or pressure on surgeons that influenced their testimony.

As for evidence of SpineFrontier's disclosures since 2013, which constitutes *Brady* material, the government denied during the extensive meet-and-confer efforts any obligation to produce CMS records concerning those disclosures. According to the government, despite CMS being part of HHS and a purported "victim" in the related civil action, and despite HHS OIG having participated in the joint civil and criminal investigation, the government believes that it has no duty to gather this exculpatory information because, in its view, CMS is technically "not part of the prosecution team." In taking that position, the government disregards prior Orders in this case imposing broad *Brady* obligations that require production of all exculpatory information,

including material arising from the joint civil investigation, where CMS was the alleged victim.

Finally, the government takes superficial positions on the meaning of “willfulness” in the AKS, in that it relies on only a case in which parties did not litigate nuanced aspects of willfulness under the AKS, and ignores directly on-point caselaw contrary to its positions. To assist the Court in the assessment of how misleading information tainted the Grand Jury’s decision to indict, the Court should conduct an *in camera* inspection of portions of Grand Jury transcripts that have been withheld, including instructions of law.

The government is expected to fight hard when prosecuting cases, but it is also required to fight fair. Here, the government crossed the line by misleading the Grand Jury about proper disclosures of consulting payments, withholding *Brady* material about those disclosures in CMS’s possession, and using the false claim that SpineFrontier failed to make required disclosures to support the government’s misguided charge that the defendants willfully violated the AKS.

Background

Indictment

On August 30, 2021, the Grand Jury returned the Indictment, alleging a scheme by which the defendants allegedly paid consulting fees to surgeons for services related to their use of SpineFrontier’s products. Count One charges a conspiracy to violate, and Counts Two through Seven charge substantive violations of, the federal AKS, 42 U.S.C. § 1320a-7b(b)(2).² Count Eight

² In the Indictment’s caption, Counts Two through Seven are labeled as violations of 42 U.S.C. § 1320a-7b(b)(2), which applies to those who “knowingly and willfully offer[] and pay[] any remuneration.” Consistent with that citation, the substantive allegations of Counts Two through Seven allege that the defendants “did knowingly and willfully offer and pay remuneration.” (Indictment ¶ 42.) The heading for Counts Two through Seven, however, cite to both § 1320a-7b(b)(2) and (b)(1). The latter applies to those who *solicit or receive* remuneration. There is no allegation that the defendants solicited or received remuneration, only that they offered and paid remuneration. The defendants thus assume that the reference to § 1320a-7b(b)(1) is merely a scrivener’s error, which should be stricken from the Indictment. If the government contends

charges a conspiracy to commit money laundering in violation of 18 U.S.C. § 1956(h), which is the subject of a separate motion to dismiss.

The following allegations are taken from the Indictment and described here only for purposes of this motion. Beginning in October 2013, IME managed the process by which surgeons submitted hours and received payments from or on behalf of SpineFrontier for consulting. *See* Indictment ¶ 4. Chin was the principal owner of IME. *Id.* The Sunshine Act requires “medical product manufacturers, such as SpineFrontier, to disclose to CMS any payment or transfer of value made to a physician, including surgeons, or a hospital, as well as any physician ownership or investment in the covered manufacturer.” *Id.* ¶ 21. Under Chin’s control, Humad and others operated IME “in part to evade Sunshine Act reporting obligations” and “to conceal the true nature of the relationship between SpineFrontier and those surgeons.” *Id.* ¶ 37.c. & 37.d.

The Indictment also alleges a failure to perform contractual obligations by consulting surgeons, in part by overstating time spent consulting. But the government has essentially conceded, at least implicitly, the facial legality of the consulting contracts – that is, assuming the surgeons had performed as they promised. Paragraphs 78 through 80 of the government’s Complaint in Intervention in the related civil action specifically alleged that (1) the contracts included an “invoicing process” that “instructed surgeons to follow” required “itemization of the activities performed, the amount of time spent . . . on each activity, and the date on which such activity was performed”; (2) the contracts prohibited consulting surgeons from including the time they spent in surgery; and (3) Humad “confirmed to a ‘consulting’ surgeon that the IME consulting agreement ‘excludes surgical time in implantation of products....’” Hence, rather than challenge

otherwise, and claims an actual intent to charge a (b)(1) violation, such a charge would give rise to multiplicity concerns that the defendants reserve the right to raise at a later, appropriate time.

the contracts themselves, the Indictment alleges that consultants failed to perform their obligations, by providing insufficient value to SpineFrontier. Of course, the mere non-performance by consultants could not by itself establish the requisite willfulness on the part of the defendants.

A review of the Indictment leaves no doubt that a critical element of the government's theory of willfulness is that the defendants used IME to pay surgeons to evade Sunshine Act reporting by SpineFrontier which, the theory goes, otherwise would expose physicians to unwanted publicity over their actual relationship with SpineFrontier. But since 2013, *SpineFrontier made the Sunshine Act disclosures*, not in IME's name, but *in SpineFrontier's own name*. SpineFrontier's disclosures to CMS of its payments to consultants reflect proper disclosures of 733 payments by SpineFrontier since just 2016. A copy of summary records from CMS's public portal is attached to the accompanying Declaration of Barry Pollack as Exhibit A. The government has refused to produce records concerning SpineFrontier's disclosures from 2013 and 2015, but in total, there exist more than 1,000 proper disclosures. This inconsistency with ¶ 37 of the Indictment and with factual predicates throughout the Indictment is far from a technical mistake by the government. In other words, the government obtained an Indictment charging Chin, Humad, and SpineFrontier with paying bribes *concealed* through IME, to show willfulness, even though the public disclosures indisputably *disclosed* that the payments came from SpineFrontier.

Efforts to Comply with the Sunshine Act

Even if the government were not required to provide the Grand Jury with exculpatory information about SpineFrontier making more than 1,000 proper Sunshine Act disclosures in its own name, and none in IME's name, the government should not have misled the Grand Jury to believe such disclosures did not exist. During meet-and-confer efforts, the government acknowledged it was aware that SpineFrontier made disclosures of itself as the payor. Likewise, the government did not deny its awareness that SpineFrontier's in-house counsel played roles in

these disclosures. Documents the government produced in discovery reflect significant efforts by SpineFrontier's counsel to make accurate Sunshine Act disclosures. A copy of an email dated June 9, 2015, for example, reflects SpineFrontier's General Counsel, Paul Speidel, communicating with Chin, Humad, and another in-house lawyer, Lesley Olson, about the completion of Sunshine Act disclosures. A copy of this email is attached to the Pollack Declaration as Exhibit B. Another email reflects efforts by Humad in 2015, working with Attorney Olson, to cure technical filing glitches and complete disclosures. A copy of this email is attached to the Pollack Declaration as Exhibit C. An email from March 30, 2017 reflects Attorney Olson again informing Humad of the completion of Sunshine Act disclosures for 2016. A copy of this email is attached to the Pollack Declaration as Exhibit D. Nevertheless, the Grand Jury transcripts produced to date reveal that the Grand Jury was deprived of meaningful information about the roles of SpineFrontier lawyers in making proper disclosures, and also was given the misleading impression that Chin and Humad drove an improper disclosure process that used IME's name to conceal SpineFrontier's identity. Yet, again, SpineFrontier's name was on the more than 1,000 disclosures, contrary to the Indictment.

Grand Jury Presentation

As reflected in the Indictment itself, the government presented to the Grand Jury misleading information that accused defendants of using IME to evade disclosure requirements. One example was hearsay testimony elicited from FBI agent Terrence Dupont about a Grand Jury exhibit. Specifically, Grand Jury Exhibit 8 consisted of an *unsigned* draft document from a salesperson (not one of the defendants) that referred to IME and the Sunshine Act. On page 18 of the Dupont testimony, from May 8, 2018, the government elicited a description of Exhibit 8. Dupont described Exhibit 8 as "a consulting packet that a SpineFrontier rep *would have given* to a prospective doctor to – who may be interested in consulting with SpineFrontier." On page 19, the agent purported to read from the document concerning the use of IME as the party with which

the physician would engage: “This protects you from the Sunshine Act and OIG, by not having to disclose working directly with a single device company, and receive anything directly from them.” Dupont did not disclose to the Grand Jury that the document was an unsigned draft, not from management, and that SpineFrontier subsequently made more than a thousand disclosures of payments to consultants *in its own name*, consistent with the Sunshine Act. Copies of relevant pages of the May 8, 2018 transcript are attached to the Pollack Declaration as Exhibit E.

On August 30, 2021, the government questioned another federal agent, Brandt Lambert, using him not just as a summary witness, but for the purpose of improperly expressing his personal opinions of probable cause based on unreliable and even unidentified hearsay. A copy of pages from the August 30, 2021 transcript is attached to the Pollack Declaration as Exhibit F. The government showed him pertinent parts of the Indictment containing, for example, allegations about the role of IME. (*See* Exhibit F, at 20.) The transcript reflects that Agent Lambert then testified, in a conclusory way that *he believed there was probable cause*:

Q And based on your participation in the investigation, and your understanding of witness interviews, witness testimony, documents obtained and other work by agents and investigators, *do you believe there is probable cause to support the allegation set forth in this count* [Count One]?

A I do.

* * *

Q And *do you believe probable cause supports each of these counts, Counts Two through Seven*?

A I do.

(*Id.* at 30, 34 (emphases added).)

The government also called certain surgeon consultants as witnesses before the Grand Jury. At least some served as cooperating witnesses. On August 17, 2020, the government sent a message by charging one of the surgeon consultants, Jason Montone, D.O., with conspiring to

violate the AKS and obstruction of justice for creating “false documents purporting to show work he allegedly performed pursuant to a consulting agreement” (although without any allegation that the defendants here participated in the obstruction or even knew about it). With respect to surgeon consultants, a defense attorney described the government’s use of threats to obtain cooperation:

In addition to my communications with the government, I have also had communications with counsel for certain witnesses whom the government has contacted. In July 2019, counsel for one witness reported to me that the government provided assurances to the witness’s counsel that the witness would not be criminally prosecuted if he agreed to a civil settlement (which he ultimately did, and was not thereafter charged). The witness’s counsel mentioned the names of the government attorneys involved in these discussions, who include attorneys who have appeared in this criminal action.

7/31/23 Declaration of Seth Orkland ¶ 8 (Doc. 109). Naturally the government wielded leverage to impact the statements of surgeon consultants through a variety of agreements or understandings that resulted in non-prosecution or other forms of leniency, immunity, or protection. Montone stood by a description of his performance until he faced charges. But others who now may claim they did not provide sufficient value to SpineFrontier as consultants (in breach of their contracts), became aware of Montone’s conviction, and found ways to avoid the government’s full wrath. The law requires greater care, caution, and corroboration for testimony by such cooperating witnesses.³

Brady Orders and Non-Compliance by the Government

Not only is the government subject to *Brady* obligations, but it is also subject to two prior Orders requiring broad disclosure of materials from the related civil case and investigation. On September 28, 2021, pursuant to the Due Process Protection Act, the Magistrate Judge issued an

³ “A witness who realizes that he may be able to obtain his freedom or receive a lighter sentence or obtain other benefits from the government by giving testimony favorable to the prosecution has a motive to testify falsely. Therefore, you must examine the testimony with greater care and caution.” *United States v. Deleon*, No. CR 07-10277-NMG, 2016 WL 3747487, at *12 n.12 (D. Mass. May 9, 2016), report and recommendation adopted, No. 07-10277-NMG, 2016 WL 3766289 (D. Mass. May 9, 2016) (approving jury instruction).

Order stating in pertinent part as follows:

[T]he United States is ordered to disclose all exculpatory information, in a timely manner, to the defendants. This information includes, but is not limited to, evidence that is material and is favorable to the accused. Specific categories of exculpatory evidence that must be provided to the defense are set out in Local Rule 116.2. The failure to discharge this obligation may result in consequences, including the reversal of any conviction, exclusion of evidence, adverse jury instructions, dismissal of charges, contempt proceedings, and/or sanctions by the Court.

Subsequently, the Magistrate Judge ruled in relation to a defense motion to compel: “[T]he court’s Order of October 13, 2023 [on the motion to compel], does require the government to review all emails and other communications between the civil and criminal teams to look for discoverable information.” 10/18/23 Order (Doc. 128).

Nevertheless, to date, the government has violated these *Brady* Orders by refusing to produce records at CMS, a department within HHS, concerning SpineFrontier’s proper disclosures, despite the government’s joint investigation with HHS OIG, treatment of CMS as its client and the victim in the related civil action, and the Magistrate Judge’s Order compelling production from files of both civil and criminal teams. When the defense learned they could not access early disclosures by SpineFrontier and that CMS possesses other types of materials concerning SpineFrontier’s disclosures, defense counsel followed up prior broad *Brady* requests with yet more specific requests. As part of meet-and-confer efforts, on December 22, 2023, defense counsel wrote to the government requesting, among other things, specific categories of *Brady* material and identified materials beyond just the proper SpineFrontier disclosures, explaining:

CMS’s system creates internal and external data responses, including but not limited to information and materials concerning Error and Warning Codes, Review and Dispute Data, Review and Correct Data, Data Displays, and communications among various stakeholders during these processes. Particularly since the Indictment charges efforts to evade reporting requirements by SpineFrontier, the government must search these materials for *Brady* material, including the identification of government employees who are witnesses to communications about SpineFrontier’s reports of payments, and all other communications and data

tending to show compliance by SpineFrontier.

A copy of this letter is attached to the Pollack Declaration as Exhibit G. During meet-and-confer efforts, the government repeatedly refused to produce these materials, arguing that CMS is (at least technically) not part of the prosecution team.⁴

Furthermore, despite the defendants raising concerns about threats (whether express or implied) made to surgeon consultants directly or through counsel, the government has refused to produce its (non-privileged) emails with counsel for cooperating witnesses. Such communications would tend to show whether there were any threats or “inducements,” or even reveal scheduling matters that could provide context and timing, in relation to witnesses’ descriptions of their performance of consulting contracts and any changes in those descriptions as compared to what they represented to SpineFrontier or claimed to the government in initial communications.⁵

⁴ After more than a month of meet-and-confer efforts in which the government refused to obtain and produce such material, the government sent an email on January 25, 2024, the day before this motion was due, saying it would now agree to request information from CMS. The government maintained its position, however, that it believes it is *not* obligated to collect and provide such information. The same email revealed that the government has been withholding information already gathered from CMS that it had not produced despite the Court’s *Brady* Orders and the meet-and-confer process. With respect to the information it had already gathered, at 2:12 pm on January 26, the afternoon on which this motion was due, the government sent a discovery letter and a production that appears to contain three documents related to CMS. The government’s letter also contained approximately five pages of narrative describing information about SpineFrontier’s Sunshine Act disclosures that the prosecution had not previously revealed, but that the letter reports CMS had provided to the prosecution team at various times over the past eight years. The government reiterated its view that while it will make additional “requests” of CMS, it has no obligation to gather exculpatory information from CMS. Given the eleventh-hour timing of these revelations, which defendants have been unable to fully review prior to this filing, and which in any event leave the defendants in the dark as to what else the government will produce from CMS, the defendants continue to include their arguments and request for relief related to this issue.

⁵ In unguarded moments of truth, Grand Jury witnesses even acknowledged being educated by prosecutors on their legal theories. For example, one witness, Amanda Dalton, testified that “over the course of time” the AUSA taught her the “pay for play” concept at meetings between them. On December 19, 2019, Ms. Dalton appeared before the Grand Jury and acknowledged under oath: “I guess that was a concern in light of pay-for-play discussions, which we’ve had over the course

The government has likewise taken narrow or misleading positions in response to discovery obligations concerning its cooperating witnesses. For example, Montone surrendered his cellular phone to the government. During motion practice concerning items withheld from Montone's phone, the government represented to the Magistrate Judge that an oral agreement with Montone prohibited the government's access to Montone's texts with his counsel. (*See, e.g.*, Doc. 110, at 5-6.) The government even suggested that the Fourth Amendment prohibited the government from turning over certain documents actually in its possession, given this supposed oral agreement. (*See* 9/13/23 Tr. at 15.) Subsequently, however, the defendants learned from a belated government production of a consent form, signed by Montone *after* the supposed oral agreement. In the consent, Montone had actually agreed to an *unconditional* waiver and to "a complete search" of the phone, including an express waiver of constitutional protections over its contents. He also stated in the signed consent that no "promises of any kind" had been provided to him in connection with his consent, thus giving the government unfettered access to all of his phone's contents, contrary to its argument on the motion to compel. Rather than disclose this consent during the dispute over the contents of Montone's phone, the government withheld it until after the motion was fully resolved. A copy of the consent is attached to the Pollack Declaration as Exhibit H.⁶

of time," and then made clear that by "we" she meant the AUSA questioning her, and her having these sorts of educational discussions "over the course of time." Other transcripts reflect vague testimony by witnesses about the government's description of these and other AKS obligations. These references further support the appropriateness of an evidentiary hearing and an *in camera* review of the government's specific instructions on the law to the Grand Jury.

⁶ On January 24, 2024, more than a month after the defendants raised issues with the government having withheld this consent until after the motion was resolved, the government sent a letter to Magistrate Judge Kelley expressing "regret" that the consent was not produced earlier. Even that letter fails to take meaningful accountability for having made arguments that were outright contradicted by the consent it had withheld. Instead, the letter takes a no-harm-no-foul attitude, by

Discussion

I. A SUBSTANTIAL LIKELIHOOD EXISTS THAT MISLEADING INFORMATION INFLUENCED THE GRAND JURY’S DECISION TO INDICT.

The Indictment has resulted from an abuse of the Grand Jury process, including false and misleading presentations and reliance on improper opinion testimony based on unreliable hearsay, which likely influenced the decision to indict. The government is not required to present exculpatory information to a grand jury, but there are well-established limits on such prosecutorial discretion. *See United States v. Stevens*, 771 F. Supp. 2d 556, 565 (D. Md. 2011). Here, cumulative effects of misconduct occurred, as described in more detail below, leading to an Indictment that on its face shows the Grand Jury was misled into believing that, contrary to undisputed evidence, SpineFrontier used the name IME in public disclosures of payments to doctors to avoid exposing publicly their relationship with SpineFrontier.

A. The Government Presented Materially False Information that Misled the Grand Jury.

While a drastic remedy, “a motion to dismiss or quash an indictment because of the absence or incompetency of evidence before the Grand Jury is addressed to the discretion of the trial court, and the decision to grant or deny the motion will not be reversed unless there has been an abuse of that discretion.” *United States v. Tane*, 329 F.2d 848, 853 (2d Cir. 1964). Despite presumptions of regularity in indictments, “due process nevertheless imposes certain restrictions on the type of evidence a prosecutor may knowingly present for grand jury consideration.” *United States v.*

noting that the Magistrate Judge rejected the government’s argument as to whether it “possessed” the phone’s contents, and arguing its position as to why, in the end, nothing meaningful was withheld from the phone. The letter never points out to Magistrate Judge Kelley, however, that the consent form permitted a “complete search” of the phone, waived constitutional protections, recited the absence of any promises, and was signed after the supposed agreement not to conduct a complete search, all of which cannot be squared with the arguments the government had made to the Court when opposing the motion to compel. A copy of the government’s letter is attached to the Pollack Declaration as Exhibit I.

Goldman, 451 F. Supp. 518, 520 (S.D.N.Y. 1978). Prosecutors cannot rely on known false information. *Id.* Here, as reflected in the Indictment itself, the government presented information that misled the Grand Jury into believing that SpineFrontier did not use its name in disclosures of payments to consultants. That information was false. While dismissal of an indictment has been described as an extraordinary remedy (a description also used for injunctive relief), prosecutors misleading a Grand Jury is an extraordinarily rare occurrence. No evidence supports the allegation in the Indictment that SpineFrontier used IME’s name on disclosures to evade reporting requirements and to conceal that SpineFrontier made the payments. Accordingly, and particularly in light of the cumulative effect of the issues discussed below, the Indictment should be dismissed.

B. The Government Deceived the Grand Jury Through Summary Opinions by a Case Agent of Probable Cause Based on Unreliable and Unidentified Hearsay.

The Second Circuit has analyzed courts’ supervisory powers over the misuse of summary opinions of probable cause based on unreliable and unidentified hearsay before the Grand Jury:

When the framers of the Bill of Rights directed in the Fifth Amendment that “No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury,” they were not engaging in a mere verbal exercise. The importance of avoiding undue reliance upon hearsay before a grand jury is heightened by this circuit’s view that an indictment constitutes a finding of probable cause and avoids the need for a preliminary hearing under F.R.Cr.P. 5 (c). *Sciortino v. Zampano*, 385 F.2d 132 (2 Cir. 1967), cert. denied, 390 U.S. 906, 88 S.Ct. 820, 19 L.Ed.2d 872 (1968).

* * * *

We have been willing to allow ample, many doubtless think too ample, latitude in the needless use of hearsay, subject to only two provisos—that the prosecutor does not deceive grand jurors as to “the shoddy merchandise they are getting so they can seek something better if they wish”.... We had hoped that, with the clear warnings we have given to prosecutors, going back to *United States v. Umans*, 368 F.2d 725, 730 (2 Cir. 1966), cert. granted, 386 U.S. 940, 87 S.Ct. 975, 17 L.Ed.2d 872 cert. dismissed as improvidently granted, 389 U.S. 80, 88 S.Ct. 253, 19 L.Ed.2d 255 (1967), and the assurances given by United States Attorneys, see *United States v. Arcuri*, *supra*, 405 F.2d at 693 & n. 4, a reversal for improper use of hearsay before the grand jury would not be required. Here the Assistant United States Attorney, whether wittingly or unwittingly—we prefer to think the latter, clearly violated the

first of these provisos. We cannot, with proper respect for the discharge of our duties, content ourselves with yet another admonition; a reversal with instructions to dismiss the indictment may help to translate the assurances of the United States Attorneys into consistent performance....

United States v. Estepa, 471 F.2d 1132, 1135-37 (2d Cir. 1972); *see also United States v. Hogan*, 712 F.2d 757, 761 (2d Cir. 1983) (“[T]he government prosecutor, in presenting hearsay evidence to the grand jury, must not deceive the jurors as to the quality of the testimony they hear.”).

Here, the government caused agents to provide summary opinions of probable cause based on unreliable and even unidentified hearsay, which deceived the Grand Jury. As described above, an agent mis-described an unsigned, undated, and unsent document, or at least described it in a materially incomplete way, which left the Grand Jury with the impression that SpineFrontier did not in fact make Sunshine Act disclosures in its own name. *See* Exhibit E (Tr. of 5/8/18), at 18-19. In reality, SpineFrontier made more than 1,000 such proper disclosures since 2013. In other problematic testimony, the government elicited from another agent his personal *opinion* that there was probable cause for various paragraphs and charges in the Indictment, including the allegations in Paragraph 37 that referred to the use of IME to evade reporting obligations, a false fact. Under these circumstances, there is a substantial likelihood that misleading information influenced the decision to indict. *See United States v. Acquest Dev., LLC*, 932 F. Supp. 2d 453, 460-62 (W.D.N.Y. 2013) (dismissing indictment where a Grand Jury was told that a judge had found probable cause for some of the crimes charged, based on risk that doing so interfered with Grand Jury impartiality and exercise of its own judgment on the ultimate issue before it); *United States v. Breslin*, 916 F. Supp. 438, 446-47 (E.D. Pa. 1996) (finding that among misconduct threatening Grand Jury’s “independent functioning” was a prosecutor telling the Grand Jury that it would easily be able to find probable cause); *see also Hogan*, 712 F.2d at 761 (finding courts must exercise supervisory power “to prevent prosecutorial impairment of the grand jury’s independent role”).

C. The Government’s Serious Misstatements of Applicable Law Add to Grave Doubt that the Decision to Indict Was Free From Influence of Misleading Information.

The AKS enforces a complex healthcare regulatory scheme. The government agrees that, to convict any defendant, it must prove that he or it acted “willfully.” While courts do not require the government to prove that a defendant knows the specific statutory citation of a law he may break, courts impose a higher standard of willfulness in cases involving highly technical regulatory regimes. While sitting in the D.C. Circuit Court, in a concurring opinion that reviews a jury instruction for plain error, Justice Kavanaugh explained:

Proper application of statutory *mens rea* requirements and background *mens rea* principles can mitigate the risk of abuse and unfair lack of notice in prosecutions under § 1001 and other regulatory statutes. In § 1001 cases, that means proof that the defendant knew that making the false statement would be a crime. To be sure, “ignorance of law is no defense” is a hoary maxim. But it does not automatically apply to today’s phalanx of federal regulatory crimes. See Wayne R. LaFare, Criminal Law § 5.6, at 298–311 (5th ed. 2010). For some regulatory offenses—particularly statutes like § 1001 that proscribe only “willful” conduct—the Supreme Court has recognized an ignorance-of-law or mistake-of-law defense, or has required affirmative proof of the defendant’s knowledge that his or her conduct was unlawful. See *Bryan v. United States*, 524 U.S. 184, 191–92, 118 S.Ct. 1939, 141 L.Ed.2d 197 (1998); *Ratzlaf v. United States*, 510 U.S. 135, 141–49, 114 S.Ct. 655, 126 L.Ed.2d 615 (1994); *Cheek v. United States*, 498 U.S. 192, 199–201, 111 S.Ct. 604, 112 L.Ed.2d 617 (1991); *Lambert v. California*, 355 U.S. 225, 229–30, 78 S.Ct. 240, 2 L.Ed.2d 228 (1957); cf. *Liparota v. United States*, 471 U.S. 419, 425–26, 105 S.Ct. 2084, 85 L.Ed.2d 434 (1985).

United States v. Moore, 612 F.3d 698, 703-04 (D.C. Cir. 2010) (Kavanaugh, J., concurring).

Consistent with Justice Kavanaugh’s opinion, in AKS cases, while not requiring proof of a corrupt intent, courts have required proof of an “intentional violation of a known legal duty.” *United States ex rel. Hart v. McKesson Corp.*, No. 15-CV-0903 (RA), 2023 WL 2663528, at *7 (S.D.N.Y. Mar. 28, 2023) (“Put differently, because the ‘AKS does not apply to those who are unaware that [(conduct constituting kickbacks)] [is] prohibited by law and accidentally violate the statute,’ the statute requires proof of an ‘intentional violation of a known legal duty.’” (editing in

original)); *see Pfizer, Inc v. United States Dep't of Health & Hum. Servs.*, 42 F.4th 67, 77 (2d Cir. 2022) (“In other words, the AKS does not apply to those who are unaware that such payments are prohibited by law and accidentally violate the statute.”); *Hanlester Network v. Shalala*, 51 F.3d 1390, 1399-400 (9th Cir. 1995) (interpreting “willful” in the AKS “as ‘a voluntary, intentional violation of a known legal duty’” (quoting *United States v. Pomponio*, 429 U.S. 10, 12 (1976))).

Without crediting this line of cases, the government has relied in meet-and-confer communications on *Bay State Ambulance & Hospital Rental Services, Inc.*, 874 F.2d 20 (1st Cir. 1989), which affirmed jury instructions concerning “willfulness.” The definition included, “[w]illfully means to do something purposely, with the intent to violate the law, to do something purposely that the law forbids.” *Id.* at 33. Unlike *McKesson*, *Pfizer*, and *Hanlester*, the First Circuit in *Bay State Ambulance* was not addressing whether willfulness in AKS cases required intentional violation of a known legal duty. Rather, the defendant was asking for an instruction that a payment equal to fair value could evidence a proper *mens rea*. The First Circuit said it was not error to refuse that particular request. There was no request for language describing “willful” that referred to “known legal duties,” so the court had no occasion to address the issue. Furthermore, even the instruction used referred to “the intent to violate the law,” which could mean the same “willful” standard as that applied by other courts. The government’s misunderstanding of the *mens rea* requirement heightens concerns regarding how it improperly influenced the Grand Jury here.

In *United States v. Stevens*, the court initially required the government to submit *in camera* the instructions on the law given to the Grand Jury, and eventually dismissed the charges. The *Stevens* court explained:

Though often referred to as the “advice of counsel defense,” this label is actually a misnomer. Good faith reliance on the advice of counsel, when proven, negates the element of wrongful intent of a defendant that is required for a conviction. *See United States v. Peterson*, 101 F.3d 375, 381 (5th Cir.1996) (“A good faith reliance

on the advice of counsel is not a defense to securities fraud. It is simply a means of demonstrating good faith and represents possible evidence of an absence of any intent to defraud.”); *see also Oakley, Inc. v. Bugaboos*, 2010 U.S. Dist. LEXIS 123976, *11–12 (S.D.Cal. Nov. 23, 2010) (just because the “‘advice of counsel defense’ contains the word defense ... does not an affirmative defense make.”)

An affirmative defense is “[a] defendant’s assertion of facts and arguments that, if true, will defeat the plaintiff’s or prosecution’s claim, even if all the allegations in the complaint are true.” Black’s Law Dictionary 482 (9th ed. 2009). By contrast, the advice of counsel “defense” negates the defendant’s wrongful intent, and therefore demonstrates an absence of an element of the offense—*mens rea*.

Stevens, 771 F. Supp. 2d at 565. The court continued:

[W]here a prosecutor’s legal instruction to the grand jury seriously misstates the applicable law, the indictment is subject to dismissal if the misstatement casts “grave doubt that the decision to indict was free from the substantial influence” of the erroneous instruction. *United States v. Peralta*, 763 F.Supp. 14, 21 (S.D.N.Y.1991) (citing *Bank of Nova Scotia v. United States*, 487 U.S. 250, 256, 108 S.Ct. 2369, 101 L.Ed.2d 228 (1988)).

In *United States v. Peralta*, a highly analogous case, the district court dismissed an indictment after finding that the prosecutor seriously misinstructed the grand jury regarding the elements of constructive possession ... [that] left “grave doubt that the decision to indict was free from the substantial influence” of the prosecutor’s erroneous instruction. *Id.* at 21.

* * * *

As discussed, *supra*, good faith reliance on the advice of counsel negates a defendant’s wrongful intent, and is therefore highly relevant to the decision to indict. A proper instruction would have informed the grand jurors that if Stevens relied in good faith on the advice of counsel, after fully disclosing to counsel all relevant facts, then she would lack the wrongful intent to violate the law and could not be indicted for the crimes charged in the proposed indictment.

Id. at 566-67 (editing in original). Given the obvious flaw in the Indictment designed to satisfy “willfulness,” but that contradicts more than 1,000 actual disclosures in SpineFrontier’s own name rather than in IME’s name, as well as the government’s superficial stance on willfulness for an AKS violation, the government’s Grand Jury presentation is potentially even more problematic than in *Stevens*. This Court should therefore dismiss the AKS charges. Should the Court conduct an evidentiary hearing prior to determining the proper remedy, the Court should require, as part of

that process, that the government submit all Grand Jury transcripts, including instructions on the law, for an *in camera* inspection to assess the totality and impact of prosecutorial misconduct.

II. THE GOVERNMENT HAS VIOLATED ITS *BRADY* OBLIGATIONS, INCLUDING TWO PRIOR *BRADY* ORDERS, BY NOT COLLECTING AND PRODUCING (1) ALL RECORDS CONCERNING SPINEFRONTIER'S DISCLOSURES TO CMS, AND (2) COMMUNICATIONS WITH COOPERATING WITNESSES AND THEIR COUNSEL.

As described above, this Court has so far issued two Orders that impose broad *Brady* obligations on the government. Despite those Orders, the government has failed to produce exculpatory records concerning SpineFrontier's disclosures of payments that name SpineFrontier, not IME, as the source of consulting payments to doctors. Obviously, such records are exculpatory and fall within the core of *Brady* material. Yet the government claims it is not required to contact CMS for this information. Thus, in this prosecution investigated by HHS, which turns at least in large part on disclosures to HHS's own CMS department, and with the government having represented CMS as a victim in the related civil action, the government apparently never gathered this exculpatory information from CMS. It plainly has access to this evidence, but has, at least until the eve of this motion (*see* note 4 above), improperly refused to search for and produce it.

Other courts have treated exculpatory records at CMS or its parent agency, HHS, as *Brady* material for federal prosecutors pursuing health care kickback charges. *See United States v. Pikus*, 39 F.4th 39, 46 (2d Cir. 2022) (dismissing charges on speedy trial grounds, while noting "the Government also reasserted its position that the documents were not *Brady* material, because they were in the possession of other agencies," but "the Court continued to treat documents in the possession of HHS and other agencies as potential *Brady* material and subject to disclosure if their content was exculpatory"). CMS is too closely connected to the prosecution to excuse the government from doing investigative work, including the collection of actual disclosures by SpineFrontier. If the charges are not dismissed, the government should be required to produce all

documents concerning SpineFrontier's disclosures to CMS in its own name.

This prosecution has been plagued by false and misleading government representations and presentations, including material omissions. The Grand Jury was misled as to SpineFrontier's supposed use of IME to conceal SpineFrontier's role in paying physicians, as discussed herein. The government produced an Indictment that falsely claimed that concealing SpineFrontier's role was the purpose of working through IME. When resisting discovery of material in its possession from Montone, it withheld a critical signed consent form. Hence, the Court cannot simply accept the government's pattern of superficial assurances that it understands its *Brady* obligations and has behaved appropriately in securing the Indictment from the Grand Jury. The cumulative prejudice from improper Grand Jury processes and disregard of *Brady* obligations requires dismissal of the AKS charges. At the very least, this Court should conduct an evidentiary hearing and an *in camera* inspection. A full evidentiary record, including examination of Agent Dupont, would shed light on the government's failure to inform the Grand Jury of literally more than 1,000 disclosures by SpineFrontier that contradict the spirit and the letter of the Indictment as a whole, the government's refusal to produce exculpatory CMS records, and the scope of its interactions, threats, agreements, and understandings with the surgeon consultants.

Conclusion

Based on the foregoing, the defendants respectfully request that the Court dismiss Counts One through Seven. If the Court determines it needs further information prior to dismissal, the defendants respectfully request an evidentiary hearing concerning the government's awareness of SpineFrontier's disclosures, aided by disclosure of the government's communications with cooperating witnesses and their counsel, and an *in camera* inspection of all withheld Grand Jury transcripts, including those that relate to the presentation of AKS charges and instructions of law.

Respectfully submitted,

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Certificate of Service

The undersigned certifies that this document, filed through the ECF system, will be electronically served on counsel who are registered users of ECF on January 26, 2024.

/s/ Barry S. Pollack